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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/696,940

10/30/2003

Daniel L. Flynn

2932/3A-US

9087

7590
Pharmacia Corporation
Global Patent Department
P. O. Box 1027
St. Louis, MO 63141

01/17/2007



EXAMINER

RAMACHANDRAN, UMAMAHESWARI

ART UNIT

PAPER NUMBER

1617

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
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31 DAYS

01/17/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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DETAILED ACTION

Claims 35-59 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims (in part) 35-46, drawn to compounds, simple composition of generic formula II of claim 35 wherein R8 is non-heterocycle, classified in classes 558-568, subclasses various depending on the nature of the substituents of R1-R3, Y. If this group is elected further restriction/election may be required as there are many unknowns.
- II. Claims (in part) 35-46, drawn to compounds, simple composition of generic formula II of claim 35 wherein R8 is heterocycle, classified in classes 544, subclasses various depending on the nature of the substituents of R1-R3, Y. If this group is elected further restriction/election may be required as there are many unknowns.
- III. Claims (in part) 47-53, drawn to a method of treating herpes viral infection in a subject, comprising administering an effective amount of compound of formula II in claim 47, wherein R8 is non-heterocycle, classified in classes 558-568, subclasses various depending on the nature of the substituents of R1-R3, Y. If this group is elected further restriction/election may be required as there are many unknowns.
- IV. Claims (in part) 47-53, drawn to a method of treating herpes viral infection in a subject, comprising administering an effective amount of compound of

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formula II in claim 47, wherein R8 is heterocycle, classified in classes 544, subclasses various depending on the nature of the substituents of R1-R3, Y. If this group is elected further restriction/election may be required as there are many unknowns.

- V. Claims (in part) 35, 54-57, drawn to a method of inhibiting a viral protease, said method comprising treating subject with an effective amount of a compound of formula II in claim 35, wherein R8 is non-heterocycle, classified in classes 558-568, subclasses various depending on the nature of the substituents of R1-R3, Y. If this group is elected further restriction/election may be required as there are many unknowns.
- VI. Claims (in part) 35, 54-57, drawn to a method of inhibiting a viral protease, said method comprising treating subject with an effective amount of a compound of formula II in claim 35, wherein R8 is heterocycle, classified in classes 544, subclasses various depending on the nature of the substituents of R1-R3, Y. If this group is elected further restriction/election may be required as there are many unknowns.
- VII. Claims (in part) 35, 58, 59, drawn to a method of prophylactic treatment of herpes viral infection in a subject, said method comprising treating subject with an effective amount of a compound of formula II in claim 35, wherein R8 is non-heterocycle, classified in classes 558-568, subclasses various depending on the nature of the substituents of R1-R3, Y. If this group is

elected further restriction/election may be required as there are many unknowns.

- VIII. Claims (in part) 35, 58, 59, drawn to a method of prophylactic treatment of herpes viral infection in a subject, said method comprising treating subject with an effective amount of a compound of formula II in claim 35, wherein R8 is heterocycle, classified in classes 544, subclasses various depending on the nature of the substituents of R1-R3, Y. If this group is elected further restriction/election may be required as there are many unknowns.

The inventions of Groups I and II and III - VIII are distinct from each other because of the following reasons: Inventions of Groups I-II and III -VIII are related as process of making and process of using the product. The inventions are distinct if either or both of the following can be shown: (1) that the method as claimed can be carried out with a different product or (2) that the product as claimed can be used for a different method. In the instant case the method in the claims can use different anti viral products as taught by Horrobin et al (U.S. 5,276,020). Also, the product as claimed can be used for treating other viral infections.

In addition, the group inventions III – VIII are distinct for the following reasons: Groups III and IV are drawn to a method of treating herpes viral infection in a subject with non-heterocycle and heterocycle compounds of formula II of claim 35, groups V and VI are drawn to a method of inhibiting a viral protease with non-heterocycle and heterocycle compounds of formula II of claim 35, and groups VII and VIII are drawn to a

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method of prophylactic treatment of herpes viral infection in a subject, with non-heterocycle and heterocycle compounds of formula II of claim 35.

The searches of Groups I -VIII may be overlapping but there is no reason to believe that the searches would be co-extensive. The search required for inventions of Groups I and II is not required for Groups III-VIII, restriction for examination purposes as indicated is proper. The examiner will be focusing on the patentability of the method and not the composition for the group for Groups III – VIII searches. Conversely, in searching for Groups I- II, the examiner will be focusing on the patentability of the composition and not the method of treatment. The search for all inventions would place an undue burden on the Office in view of the corresponding diversity in the field of search for each.

The examiner has required restriction between process and product claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection is governed by 37 CFR 1.116; amendments submitted after allowance is governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process

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claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between products claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

The application contains claims directed to patentably distinct species of the claimed invention. If applicant elects group I or II, applicant is required to elect a single species with all the variables exactly and definitely disclosed from claims 35-46. If applicant elects group III or IV, applicant is required to elect a single species with all the variables exactly and definitely disclosed from claims 47 -52 and further elect herpes virus from the list in claim 53. If applicant elects groups V or VI, applicant is required to elect a single compound from claim 35 and further elect a species from claim 56. If

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applicant elects groups VII or VIII, applicant is required to elect a single compound from claim 35 and further elect herpes virus from the list in claim 59.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly

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and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C 103(a) of the other invention.

Election

A telephone call to the attorney is not required where 1) the restriction requirement is complex, 2) the application is being prosecuted pro se, or 3) the examiner knows from past experience that a telephone election will not be made (MPEP § 812.01). Therefore, since the examiner knows from past experience that written restriction is preferred, a telephone election was not made.

Conclusion

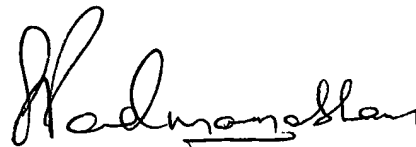
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Umamaheswari Ramachandran whose telephone number is 571-272-9926. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER

| | | | |
|-----------------------------------|---------------------------------------|--|-------------|
| Notice of References Cited | Application/Control No. 10/696,940 | Applicant(s)/Patent Under Reexamination FLYNN ET AL. | |
| | Examiner Umamaheswari Ramachandran | Art Unit 1617 | Page 1 of 1 |

U.S. PATENT DOCUMENTS

| * | | Document Number Country Code-Number-Kind Code | Date MM-YYYY | Name | Classification |
|---|---|--|-----------------|-----------------|----------------|
| * | A | US-5,276,020 | 01-1994 | Horrobin et al. | 514/45 |
| | B | US- | | | |
| | C | US- | | | |
| | D | US- | | | |
| | E | US- | | | |
| | F | US- | | | |
| | G | US- | | | |
| | H | US- | | | |
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| | J | US- | | | |
| | K | US- | | | |
| | L | US- | | | |
| | M | US- | | | |

FOREIGN PATENT DOCUMENTS

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| | T | | | | | |

NON-PATENT DOCUMENTS

| * | | Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages) |
|---|---|---|
| | U | |
| | V | |
| | W | |
| | X | |

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

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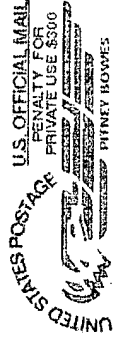
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